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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15/01/2003
C(2003) 318

NOT FOR PUBLICATION

COMMISSION DECISION

of 15/01/2003

amending Decision C(1999) 939 on the marketing authorization for the medicinal product for human use

"Cetrotide - Cetrorelix (as acetate)"

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC.

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"Cetrotide - Cetrorelix (as acetate)"

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2],

Having regard to Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93[3], as amended by Commission Regulation (EC) No 1069/98[4], and in particular Article 8(3) thereof,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products,

Whereas:

(1) The medicinal product "Cetrotide - Cetrorelix (as acetate)" entered in the Community register of medicinal products under Nos EU/1/99/100/001-003 authorised by Commission Decision C(1999) 939 of 13 April 1999, as amended, complies with the requirements set out in Regulation (EEC) No 2309/93.

(2) Serono Europe Ltd. submitted an application on 26 July 2002 pursuant to Article 6(1) set out in Regulation (EC) No 542/95.

(3) The European Agency for the Evaluation of Medicinal Products delivered a favourable opinion formulated on 17 October 2002 by the Committee for Proprietary Medicinal Products,

(4) Decision C(1999) 939 should therefore be amended accordingly.

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[1] OJ No L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ No L 55, 11.3.1995, p. 15
[4] OJ L 153, 27.5.1998, p. 11

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(1999) 939 is amended as follows:

1. Annex I is replaced by the Annex to this Decision.

Article 2

This Decision is addressed to Serono Europe Ltd., 56, Marsh Wall, London E14 9TP, United Kingdom.

Done at Brussels, 15/01/2003

For the Commission
Erkki LIIKANEN
Member of the Commission